United States District Court,
D. Delaware.

CORDIS CORPORATION and EXPANDABLE GRAFTS PARTNERSHIP,
Plaintiffs.
v.
ADVANCED CARDIOVASCULAR SYSTEMS, INC.; Guidant Corporation; Arterial Vascular Engineering, Inc.; Boston Scientific Corporation; and Scimed Life Systems, Inc,
Defendants.

No. CIV. A. 97-550-SLR

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MEMORANDUM OPINION

ROBINSON**, District J.**

I. INTRODUCTION

Pending before the court is a motion for preliminary injunction filed by plaintiffs Cordis Corporation and

Expandable Grafts Partnership (hereinafter referred to collectively as "Cordis") against defendant Advanced Cardiovascular Systems, Inc. (hereinafter referred to as "ACS"). (D.I.140) At issue is U.S. Patent No. 5,102,417 (the " '417 patent") and Cordis' charge that the ACS "MULTI-LINK" stent FN1 (hereinafter referred to as the "MULTI-LINK") infringes claims 17 and 25 of the '417 patent.

FN1. The word "stent" does not appear in the '417 patent, it being relatively new nomenclature in this field. The court understands that the word "stent" in the context of this litigation describes a device which, when expanded within a blood vessel narrowed or occluded by disease, serves as scaffolding to reopen and support the vessel. A "stent" generally refers to any device used to hold in place various materials, as first described by Charles Stent, a nineteenth century English dentist. (PX 379)

For the reasons that follow, Cordis' request for injunctive relief shall be denied.

II. FACTS

The '417 patent issued in 1992 as a continuation-in-part to U.S. Patent Nos. 4,739,762 (the " '762 patent") and 4,733,665 (the " '665 patent"), both of which issued in 1988. All three of these patents are entitled "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft." As summarized in the '762 and '665 patents,

[t]he invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

(PX 7/API 3: '665 patent, col. 1, lns. 11-17; D.I. 63: '762 patent, col. 1, lns. 19-25) The specification describes the expandable intraluminal graft as follows:

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular shaped member; the tubular shaped member having a first diameter which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen; and the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway.

* * *

The expandable intraluminal vascular graft, method for expanding the lumen of a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation

techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

(PX 7/API 3: '665 patent, col. 3, lns. 20-39; col. 4, lns. 41-53; D.I. 63: '762 patent, col. 3, lns. 32-51; col. 4, lns. 62-68; col. 5, lns. 1-7) (emphasis added).

By the time the '417 patent application was filed in 1988, the inventors recognized that,

[f]or repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the length of the body passageway which requires repair, as by the insertion of a tubular prosthetic graft, may present problems if the length of the required graft cannot negotiate the curves or bends of the body passageway through which the graft is passed by the catheter. In other words, in many instances it is necessary to support a length of tissue within a body passageway by a graft, wherein the length of the required graft exceeds the length of a graft which can be readily delivered via a catheter to the desired location within the vascular system. Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes.

(PX 1/API 1: '417 patent, col. 3, lns. 5-21) Consequently, the '417 patent, although mirroring the '665 and '762 patents, added

[a] further feature ... that at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members. Another feature of the present invention is that ... at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members. An additional feature of the present invention is that at least one connector member may be a thin-walled, spiral member, coplanar with adjacent tubular members.

(PX 1/API 1: '417 patent, col. 4, lns. 8-18) (emphasis added). Accordingly,

[t]he expandable intraluminal vascular graft, method for implanting a plurality of prostheses within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevent recoil of the body passageway; prevents erosion of the body passageway by the expanded grafts; permits expansion of the graft to a variable size dependent upon conditions within the body passageway; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

(PX 1/API 1: '417 patent, col. 5, lns. 26-43) (emphasis added).

Although the commercial embodiment of the '655/'762 patents was available abroad in 1989, it was generally recognized that "because of its rigidity, it wasn't widely applicable to the coronary circulation." (D.I. 167 at 587) Indeed, in 1988 (when the application for the '417 patent was filed), there was widespread skepticism about the efficacy of stenting. (PX 378, 383) After the '417 patent application was filed and the

commercial embodiment thereof was made available,FN2 two randomized clinical trials were initiated in 1991, one in North America and one in Europe, to compare the clinical success of the Palmaz-Schatz stent with balloon angioplasty.

FN2. Hereinafter referred to as the "Palmaz-Schatz" stent, described as "two rigid 7-mm slotted stainless steel tubes connected by a 1-mm central bridging stent." (PX 76 at 497)

The results of these trials, the Benestent trial in Europe and the STRESS trial in North America, were published in August 1994 and "demonstrated beyond reasonable doubt that stenting could improve upon the results of plain balloon angioplasty." (D.I. 167 at 591; *see also* PX 75, 76, 77, 78; API 159) The Palmaz-Schatz stent was introduced in the United States in the summer of 1994. Sales grew from 5,000 units per month in 1994 to a high of over 40,000 units per month in April/May of 1997. (D.I. 168 at 781)

The Benestent and STRESS trial results not only encouraged sales of the Palmaz-Schatz stent, they also fostered "a frenzy of activity ... [in] the stent development industry," leading to "[a] diverse variety of stents ... becoming clinically available" internationally. (PX 379 at 888)

ACS's coronary stent project began in 1987. The basic design of the MULTI-LINK was finalized in 1990, and the first clinical experience with the MULTI-LINK was in 1994. (D.I. 169 at 1017, 1061-62) ACS initiated the FDA review process in July 1995 and in November, the MULTI-LINK was launched commercially on the international market.FN3 (D.I. 169 at 1065, 1072-73) There followed during the years 1995-97 a series of clinical trials, culminating in the ASCENT trial, a "randomized, multicenter comparison of the ACS MULTI-LINK coronary system with the Palmaz-Schatz stent." (D.I. 169 at 1062-63; PX 257) As to the preselected primary, secondary, and tertiary end points, there were no statistically significant differences reported. (D.I. 166 at 346) The ASCENT trial proved, therefore, that the ACS MULTI-LINK coronary system was equivalent to the Palmaz-Schatz stent, as required for FDA approval. (D.I. 166 at 348, 353) In addition to the preselected primary, secondary, and tertiary end points, ACS has reported the results of 108 other comparisons using the ASCENT data, five of which had a P value of .05.FN4 (D.I. 166 at 366-7)

FN3. The MULTI-LINK has been manufactured domestically since 1995 and its development has been a matter of public record. (D.I. 169 at 1071-74)

FN4. The confidence interval for the ASCENT trial was $P<.05$. As a matter of statistics, using a confidence interval of .05, if one conducts 100 comparisons and there is no difference between the groups being compared, one would expect to find five statistically significant differences due to chance alone. (D.I. 166 at 354-58) Nevertheless, one of the five comparisons involved the 30-day death rate and that result, while not statistically significant, has some clinical significance because doctors make decisions based upon such data. (D.I. 168 at 894-95)

ACS received FDA approval on October 2, 1997 and launched the MULTI-LINK commercially the next day. Since then, the MULTI-LINK has achieved in excess of 70% of the market FN5 with a selling price equivalent to or above that of the Palmaz-Schatz stent. (D.I. 169 at 1021-22) Cordis' sales have responded to competitive launchings. For the period June and July of 1997, Cordis' monthly stent sales dropped from

approximately 37,000 units to 25,000 units upon the release of two new products from Cook and Medtronic.FN6 Cordis' monthly sales rebounded in August 1997 to approximately 33,000 sales per month and has declined since then to less than 10,000 units per month. (PX 536-A) Cordis' market share has dropped from 90-95% to 20 or 25%. (D.I. 168 at 794) The loss of market leadership generally involves not only lost sales, but a loss of reputation, declining morale, and less resources to devote to maintaining a technological edge.FN7

FN5. Some of ACS's initial share may be attributed to the fact that physicians to maintain their edge like to try new devices. (D.I. 168 at 790, 808, 929-30) In the event the United States stent market becomes fragmented as it is in Europe, it is Cordis' estimate that both it and ACS will achieve market shares "in the twenties." (D.I. 168 at 810-11) In terms of the size of the market, there is evidence that the market itself would grow due, *inter alia,* to the introduction of new products (including Cordis' new products) and changes in Medicaid reimbursement for stenting procedures. (D.I. 168 at 802-03, 924; D.I. 169 at 1024, 1040-42, 1054-55)

FN6. Cordis granted licenses to Cook and Medtronic due to its history of competing effectively against these companies and their products. (D.I. 168 at 790-93)

FN7. Cordis represented that, as market leader, it had unique access to new ideas, thus giving it an edge in a "very strongly technology-driven marketplace" (D.I. 168 at 795-99), an edge it has allegedly lost since the commercial launch of the MULTI-LINK. The record demonstrates, however, that Cordis did not introduce any new technology into the stent market from 1994 (when the Palmaz-Schatz stent was commercially launched) until after the filing of this lawsuit. Although Dr. Buller praised this stability in design as helpful to the medical community (D.I. 167 at 622), it is somewhat inconsistent with Cordis' litigation position.

III. STANDARD OF REVIEW

The framework for analyzing a request for injunctive relief at the preliminary stages of litigation rests upon two fundamental principles: a preliminary injunction constitutes extraordinary relief and the grant or denial of such relief is within the discretion of the court. *See generally,* Bell & Howell Document Management Products co. v. Altek Systems, 132 F.3d 701, 704 (Fed.Cir.1997). These underpinnings are not absolute, however, and the court's discretion "must be measured against the standards governing the issuance of an injunction." Hybritech Inc. v. Abbot Laboratories, 849 F.2d 1446, 1451 (Fed.Cir.1988).

To obtain a preliminary injunction pursuant to 35 U.S.C. s. 283, a party must demonstrate that: 1) it has a reasonable likelihood of success on the merits; 2) it would suffer irreparable harm if the injunction were not granted; 3) the balance of relative hardships tips in its favor; and 4) an injunction would not have a negative impact on the public interest. *See id.*

These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.

Id.

IV. ANALYSIS

A. Likelihood of Success

It is Cordis' burden to demonstrate that, if this controversy were to be tried, Cordis would prevail in proving (by a preponderance of the evidence) that ACS is infringing the '417 patent and ACS would not successfully prove (by clear and convincing evidence) that the '417 patent is invalid. If Cordis "clearly establishe[s] a likelihood of success, it [is] entitled to a rebuttable presumption that it would be irreparably harmed if a preliminary injunction were not to issue." Bell & Howell, 132 F.3d at 705.

1. Literal Infringement

Literal infringement involves a two-step determination: the proper construction of the asserted claims and a determination whether the claims as properly construed read on the accused product or method. *See id*. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

The principles of claim interpretation are well established in the law. The exercise begins always with the claim language, which defines the scope of the claim. *See* York Prods., Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed.Cir.1996). In analyzing claim language, the court must employ "normal rules of syntax," Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1553 (Fed.Cir.1997), for "[a] claim must be read in accordance with the precepts of English grammar." In re Hyatt, 708 F.2d 712, 714 (Fed.Cir.1983). The court must ascribe to any technical term used in a claim "the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." Hoechst Celanese Corp. v. BP Chemicals Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996).

In order to give context to the claim language, the court must review as well the specification.

> The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication .... As we have repeatedly stated, "[c]laims must be read in view of the specification, of which they are a part." ... The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use it. Thus, the specification is always relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.
>
> Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

The last source of intrinsic evidence relevant to claim interpretation is the prosecution history of the patent, if it has been made part of the record.

> This history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims.
>
> The claims, specification, and file history ... constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors are entitled to review the public record,

apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention.

Id. at 1583. In order to further the "fair notice function of the requirement that the patentee distinctly claim the subject matter disclosed in the patent from which he can exclude others temporarily," Athletic Alternatives, Inc. v. Prince Manufacturing, Inc., 73 F.3d 1573, 1581 (Fed.Cir.1996), extrinsic evidence of claim interpretation, such as expert testimony, is not encouraged by the Federal Circuit. *See, e.g.,* Vitronics Corp., 90 F.3d at 1583.

a. Claim Construction

The claims at issue, claims 17 and 25 of the '417 patent, are a method claim and an apparatus claim, respectively. Claim 17 reads:

A method for expanding the lumen of a body passageway comprising the steps of:

connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts;

inserting the plurality of connected intraluminal grafts, disposed upon a catheter, into the body passageway until the grafts are disposed adjacent a desired location within the body passageway; and

expanding a portion of the catheter to provide controllable expansion of the intraluminal grafts radially, outwardly into contact with the body passageway, by deforming a portion of the intraluminal grafts with a force in excess of the elastic limit of the portion of the intraluminal grafts, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the intraluminal grafts prevent the body passageway from collapsing and decreasing the size of the expanded lumen, and the intraluminal [g]rafts remain in the passageway.

(PX 1/API 1: '417 patent, col. 14, lns. 39-59) Claim 25 reads:

An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the

application from the interior of the tubular members of a radially, outwardly extending force, which second

diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

(PX 1/API 1: '417 patent, col. 15, lns. 19-40)

At this preliminary stage of the proceedings, the parties have focused their contraventions on the following language: FN8

FN8. The court notes that its claim construction is preliminary as well.

17. A method for expanding the lumen of a body passageway comprising the steps of:
connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts; ...

* * *

25. An expandable intraluminal vascular graft, comprising: ...

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; ....

The first element in claim 17 that requires construction is the phrase "connecting a plurality of intraluminal grafts." To "connect" means to join or fasten together. *Webster's II New College Dictionary,* (1995) at 239. A "plurality" means at least two. *Webster's* at 849. "Intraluminal" means within the inner open space of a tubular organ such as a blood vessel or other body passageway. *Webster's* at 581, 650. A "graft" is a structure that is "implant [ed] ... surgically ... to compensate for a defect" in a body organ or tissue. *Webster's* at 483. Therefore, an "intraluminal graft" is a structure designed for use within the lumen of a body passageway to compensate for a defect in said passageway. (PX 1/API 1: '417 patent, col. 1, lns. 28-32; col. 6, lns. 23-54; col. 9, lns. 6-13) Neither the specification nor the claim language require that the intraluminal grafts be of any particular length; the court concludes, however, that each such "graft" must be functional, as would be expected in a method claim such as claim 17.

The next element in dispute in claim 17 is the phrase "by at least one flexible connector member disposed between adjacent grafts ." "Flexible" means capable of being bent or flexed. *Webster's* at 427. A "connector member" is a structure disposed or particularly arranged between adjacent grafts in order to join them together. The word "flexible" clearly modifies the phrase "connector member." Although it is a purpose of the invention to describe an intraluminal graft "able to flexibly bend, or articulate, with respect to the longitudinal axis of [the] graft" (PX 1/API 1: '417 patent, col. 12, lns. 44-5), there is no requirement in the claim language that each individual graft be flexible, only that the connector member be flexible. This interpretation is consistent with the disputed language of claim 25, which more specifically requires that the connector member be particularly arranged "to flexibly connect" adjacent structures; again, it is the connector member and not the adjacent structures which must provide flexibility, as is the case with the Palmaz-Schatz stent.

Claim 25 is an apparatus claim which specifically describes an "expandable intraluminal vascular graft" as

comprising at least two "thin-walled tubular members" "flexibly connected" by "at least one connector member." A "tubular member" is a structure that "ha[s] the form of a tube," i.e., is hollow and cylindrical in shape. *Webster's* at 1185. The claim further requires that each tubular member have two ends and a "wall surface" disposed or particularly arranged between the two ends, which "surface" has a "substantially uniform thickness" FN9 and more than one slot arranged "substantially parallel to the longitudinal axis of each tubular member." There is no requirement that a tubular member be any certain length, so long as it is long enough to contain more than one slot. A "slot" is "a long narrow groove, opening or notch." *Webster's* at 1039.

FN9. The word "surface" describes "the exterior or outside of an object or body" or "a two-dimensional locus of points." *Webster's Third International Dictionary* (16th Ed.1971) at 2300. Surfaces, therefore, generally do not have a thickness.

b. Infringement analysis

The MULTI-LINK is described in ACS literature as comprised of "12 rings linked by 33 articulations for flexibility" (PX 38); "a small latticed stainless steel tube" (PX 52-A); "[c]ut from a tube for optimal radial strength [and having] 33 links for flexibility and conformability" (PX 63). The MULTI-LINK is the commercial embodiment of U.S. Patent No. 5,421,955 (the " '955 patent"), which describes the stent of the invention as generally including

a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and are preferably positioned to prevent warping of the stent upon the expansion thereof. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced longitudinally close enough so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so close as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively giving a stent which is flexible along its length and about its longitudinal axis but which is still very stiff in the radial direction in order to resist collapse.

(PX 46: '955 patent, col. 1, lns. 59-68; col. 2, lns. 1-12) Beverly Huss, Vice President of ACS' Business Unit, testified that the MULTI-LINK is composed of 12 rings. Each ring is approximately 1 .2 millimeters in length. Adjacent rings are connected longitudinally by three links that are 120 degrees apart. Each ring is a "metal strut" defined by "W's and U's," "the center portion of the 'W' represent[ing] the link to the next adjacent ring." (D.I. 169 at 1077-78) According to Ms. Huss, "[t]he function of the links is to keep the rings stable and positioned correctly relative to one another so that ... the rings don't move generally out of the plane of the stent." (D.I. 169 at 1080) Ms. Huss testified that "[b]ending primarily occurs in the 'U's' and 'W's.' If there is any bending in the links, it would be minimal." (D.I. 169 at 1082) Cordis' expert testified that, when he bent a MULTI-LINK and magnified the image, he observed that "the links were actually bending," not just the "W's" and "U's" of the rings. (D.I. 167 at 482; PX 519 A, B, C)

The court concludes that Cordis has not carried its burden of persuasion as to claim 17. Although the specification of the '417 patent on occasion uses interchangeably the phrases "grafts," "prostheses," and

"tubular members" (*see, e.g.,* PX 1/API 1: '417 patent, col. 12, lns. 41-45), the court has construed the phrase "intraluminal graft" in claim 17 as requiring that each graft be functional.FN10 There is insufficient evidence of record from which the court could determine that each ring of the MULTI-LINK is a functional graft flexibly connected to another functional graft.

FN10. The court recognizes that claims 17 and 25 do not use the term "graft" consistently but does not feel compelled at this juncture to reconcile the two uses of the term.

With respect to claim 25, rather than requiring a "flexible connector member," it requires that a "connector member ... flexibly connect" adjacent tubular members.FN11 While the primary function of the 33 links of the MULTI-LINK may not be to "flexibly connect," they do connect; furthermore, they do display some flexibility and have been described by ACS as providing flexibility. Therefore, the court concludes that Cordis has carried its burden of proof with respect to claim 25 on literal infringement.FN12

FN11. In claim 17, the word "flexible" is an adjective; in claim 25, it is an adverb describing a function.

FN12. After the close of evidence, ACS submitted Cordis documents characterizing competitive stents as "coil," "hybrid," or "tube ." The Palmaz-Schatz stent was characterized as a "tube" stent; the MULTI-LINK was described as a "hybrid." This evidence may be relevant to an infringement analysis at trial. Given the court's decision at bar, however, the documents were not considered presently. (D.I.268)

2. Validity

ACS challenges the validity of the '417 patent under various theories, FN13 including obviousness under 35 U.S.C. s. 103 and failure to disclose the best mode pursuant to 35 U.S.C. s. 112 para. 1.

FN13. As an initial matter, ACS asserts that the invention of the '417 patent is being challenged in various forums. More specifically, the related '762 patent is being reexamined by the Patent Office and various foreign counterparts to the '417 patent recently have been held invalid for obviousness. (See D.I. 62; D.I. 268)

Under 35 U.S.C. s. 103, "[a] patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."

The Supreme Court has stated that the obviousness determination

lends itself to several basic factual inquiries. Under s. 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this backdrop, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of

the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Graham v. John Deere Co., 338 U.S. 1, 17-18, 69 S.Ct. 1434, 93 L.Ed. 1765 (1949). Thus, the factual inquiries relevant to the obviousness inquiry include: (1) the level of skill in the pertinent art; (2) the scope and content of the prior art as viewed through the eyes of the skilled artisan at the time of the invention; (3) the differences between the claimed invention and the prior art; and (4) relevant secondary considerations.

Included within the scope of the prior art at bar are the inventions of the related '762 and '665 patents (i.e., slotted tube grafts and tubular members), as well as several articles appearing in the publication *Radiology*. In an article published in the July 1985 volume of *Radiology,* Dr. Palmaz and others recognized that the problematic lack of longitudinal flexibility in the current graft design could be solved "by using shorter grafts or grafts in tandem." (API 33 at 76) The February and November 1986 volumes of *Radiology* featured articles co-authored by Dr. Cesare Gianturco. These articles concern self-expanding "Z" (for "zig-zag") stents connected by a wire strut, described as "allow[ing] a greater expansible force than a single long stent and provid [ing] better stabilization during release." (API 72 at 296; API 295)

The court agrees with Cordis that the primary function of the wire strut connecting adjacent Z stents was not to provide flexibility. Consistent with the court's infringement analysis, however, the wire strut unquestionably served as a connector member and (as with most wire) was at least somewhat flexible.FN14 The court concludes, therefore, that Cordis has not carried its burden of persuasion that it could withstand a challenge to the validity of the '417 patent in light of the Gianturco prior art, in combination with the '762 and '665 patents and Dr. Palmaz's 1985 article.FN15

FN14. See, e.g., API 313 at 20, where Cordis' representative describes the Gianturco prior art as exhibiting flexibility:
[I]f a wire strut looks like a hinge made of wire, flexes like a hinge made of wire, and is made of the same size wire, it is a hinge made of wire.

FN15. Given this finding, the court will not address the s. 102 challenge.

B. Irreparable Harm

Given the above findings, Cordis has not clearly established a likelihood of success on the merits and, therefore, is not entitled to a rebuttable presumption that it will be irreparably harmed if an injunction does not issue. Nevertheless, the court is mindful of the presumption of validity that inheres to the '417 patent and the court's obligation to protect the integrity of the patent system against a business mentality which places more value on obtaining market share than on honoring a competitor's intellectual property. FN16 There is no question but that allowing the MULTI-LINK to remain on the market will have adverse consequences on Cordis, including lost sales, loss of market share, tarnished reputation, diminished morale, and a negative impact on Cordis' ability to attract both dollars and ideas to maintain a competitive edge technologically. To a great extent these "harms" can be addressed by money damages. If an injunction does not issue and ACS is allowed to compete in the United States market, the court finds that ACS will be able to redress the economic harms caused by such competition should Cordis ultimately prevail at trial. (D.I. 169 at 1264-84)

FN16. It is somewhat perplexing and surely disappointing to the court that neither party sought declaratory relief prior to the commercial launch of the MULTI-LINK, despite knowledge of the product, of the market impact, and of the inevitability of a lawsuit.

C. Balance of Hardships

The court concludes that Cordis has demonstrated that it will be harmed more if an injunction does not issue than will ACS if an injunction does issue. Until October 1997, ACS had no income from its sale of the MULTI-LINK in the United States. To enjoin its activity is to re-establish the status quo circa October 2, 1997. Cordis, on the other hand, has sustained substantial losses which will not be recouped, if at all, for months. Moreover, Cordis still stands in the position of the owner of a valid patent.

D. Public Interest

The parties have devoted a great deal of their attention to the question of whether the public suffers more when efficacious medical devices FN17 are taken off the market (through, e.g., an injunction) or when efficacious medical devices never make it to the market in the first instance because the incentives offered by patent protection are no longer viable. Although the court suspects that much of this tension is generated by money-driven business decisions and not the public interest, the court concludes under the circumstances at bar that the public would be better served if an injunction did not issue.

FN17. There is no doubt that the MULTI-LINK is a useful product preferred by some physicians and which, like the Palmaz-Schatz stent, may be better suited to some medical circumstances than its competitors. The court is not inclined to make a judicial determination, however, that the MULTI-LINK is "a better stent" than the Palmaz-Schatz stent on the record presented.

V. CONCLUSION

It is the court's responsibility to weigh and measure each of the four factors deemed relevant to a preliminary injunction analysis against the other factors and against the form and magnitude of the relief requested. Having done so, the court concludes that the weight of the evidence does not support Cordis' request for injunctive relief. Mindful that a different judicial officer could well conclude otherwise, the court shall make every effort to expedite trial on the merits so as to minimize the impact of this decision.

D.Del.,1998.
Cordis Corp. v. Advanced Cardiovascular Systems, Inc.

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